

In re: Gordon Rex Paterson Dougal
Serial No.: 09/529,210
Filed: July 24, 2000
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REMARKS

Applicant hereby requests further consideration of the application in view of the amendments above and the comments that follow.

Status of the Claims

Claims 1 and 5-26 are pending in the application. Claims 1 and 5-26 stand rejected under 35 U.S.C. § 112, first paragraph. Claims 1, 6-10, 12, 15-24, and 26 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,063,108 to Salansky et al. ("Salansky"). Claims 5, 11, and 13-14 stand rejected as being unpatentable over Salansky under 35 U.S.C. § 103(a). Claim 25 stands rejected over Salansky in view of Lasers and Electro-Optics by Christopher C. Davis, Cambridge University Press 1996, page 289 ("Davis").

Objection to the Specification

The specification has been amended above to overcome the objection to the specification.

Claim rejections under § 112

The Action takes the position that the term "narrow band" in Claim 1 is a relative term rendering the claim indefinite. Applicant submits that the term is defined and understood by those of skill in the art. Nevertheless, the term has been deleted from the claim in order to expedite prosecution. Accordingly, the rejection under § 112 is now moot.

Page 3, paragraph 4 of the Action states that "[a] wavelength range of 980nm to 1300nm is cited in the disclosure. Claim 1 relates this range to a bandwidth, making the claim indefinite." Applicant submits that the bandwidth referred to is "a wavelength centered at, or about, 1072nm or at a wavelength centered at, or about, 1268nm so as to coincide with peak transmissions of a water molecule, the total bandwidth being restricted so as not to exceed the bandpass filter effect characterized by the transmission spectrum of the water molecule between 980nm and 1300nm" as recited in amended Claim 1. As shown in **Appendix D** of Applicant's response dated August 27, 2002, the bandwidths of

electromagnetic radiation centered at, or about 1072nm or at, or about 1268nm are chosen so as to coincide with peak transmissions of a water molecule in the range between 980nm and 1300nm.

The Action objects to the use of the term "and/or" in Claim 1. Claim 1 has been amended to remove the phrase "and/or." The Action also states that Claim 12 is not clear as to whether the microsecond times are for the pulse duration or treatment times. Claim 12 has been amended to read that "the pulsed electromagnetic radiation is applied for pulse duration periods of at least 10-15 μ seconds." Such amendments are made for clarification and do not relate to issues regarding the prior art.

Accordingly, Applicant submits that Claim 1 satisfies the requirements of § 112 and requests an indication of same.

Claim rejections under §§ 102(e) and 103(a) over Salansky

Claim 1 recites as follows:

1. An electromagnetic radiation therapy system comprising means for emitting divergent electromagnetic radiation at a wavelength centered at, or about, 1072nm or at a wavelength centered at, or about, 1268nm so as to coincide with peak transmissions of a water molecule, the total bandwidth being restricted so as not to exceed the bandpass filter effect characterized by the transmission spectrum of the water molecule between 980nm and 1300nm, the system being capable of producing, at the site being treated, a radiation intensity of at least 50 mWatts/cm² and up to 2 Watts/cm².

Regarding the rejection under Section 102, Applicant submits that Salansky does not disclose the claimed range with sufficient specificity. Salansky discloses a wide range of radiation wavelengths, *i.e.*, 400-2,000 nm. The present invention resides in the unexpected and hitherto unobserved phenomenon of beneficial treatment at 1072 nm or 1268 nm. Salansky does not specifically disclose either wavelength or give any specific examples falling within the claimed range. Salansky does not appreciate the therapeutic effects provided by the claimed wavelengths, and is silent to the sub-genus of wavelengths selected by the present invention.

The MPEP at § 2131.03 specifically addresses anticipation of a sub-genus by a reference disclosing a genus. In particular, MPEP § 2131.03 states (emphasis added):

When the prior art discloses a range which touches, overlaps or is within the claimed range, but no specific examples falling within the claimed range are disclosed, a case by case determination must be made as to anticipation. In order to anticipate the claims the claimed subject matter must be disclosed in the reference with "sufficient specificity to constitute an anticipation under the statute. What constitutes a "sufficient specificity" is fact dependent. If the claims are directed to a narrow range, the reference teaches a broad range, and there is evidence of unexpected results within the claimed narrow range, depending on the other facts of the case, it may be reasonable to conclude that the narrow range is not disclosed with "sufficient specificity" to constitute an anticipation of the claims. The unexpected results may also render the claims unobvious.

Applicant believes that the Action fails to establish a *prima facie* case of anticipation. However, even if the Action were to have established a *prima facie* case of anticipation, Applicant submits that Salansky does not disclose the claimed range with sufficient specificity. The claims are directed to a relatively narrow range (Claim 1 recites: "...a wavelength centered at, or about, 1072nm or at a wavelength centered at, or about, 1268nm..." (emphasis added)). Salansky proposes a broad range, *i.e.*, 400-2,000 nm. Moreover, Applicant submits that there is substantial evidence of unexpected results within the claimed narrow range as required by MPEP § 2131.03. For example, Applicant submits herewith a *Declaration of Dr. Gordon Rex Paterson Dougal under 37 C.F.R. § 1.132*, dated April 24, 2003 (hereinafter, "the Dougal Declaration").

The Examiner is directed to **Exhibits A and B** of the Dougal Declaration, which present the results of two single blind randomized clinical trials. As set forth in the Dougal Declaration, taken together, the two trials of **Exhibits A and B** compare the healing times of herpes simplex when treated with 1072 nm light and 660 nm light. The 1072 nm therapy shows unexpected improvement over conventional therapy, while the 660 nm therapy does not. Applicant submits that Salansky merely discusses one anecdotal incident of treatment with 660 nm light. As noted in the Dougal Declaration, anecdotal evidence is generally given little, if any, credibility.

The Action states that transmittance data shows that 660 nm has a higher water transmittance than 1072 nm, and concludes that if transmittance of water is a primary factor, the 660 nm wavelength should be more effective. The Action then cites the absorption coefficients given in Grove. See the Action, page 6, second paragraph. The Action further states on page 6, third paragraph, "The argument regarding restricting total bandwidth to stimulate the transmission spectrum of water is not understood."

As set forth in the Dougal Declaration, the maximum bandwidth of each light source can be defined as a "bandpass filter effect" as described by the transmission spectrum of water between 980 nm and 1300 nm. The cited art fails to recognize that this phenomenon exists where water passes 1072 nm and 1268 nm light selectively in the near infrared spectrum and provides a bandstop filter for light between 980 and 1300 nm. See **Appendix D** of Applicant's response dated August 27, 2002 (also **Exhibit A, Figure 1**).

As shown in **Exhibit A, Figure 1**, the Examiner is correct that transmittance data shows that 660 nm has a higher water transmittance than 1072 nm. However, with reference to the Dougal Declaration, it has been discovered that radiation therapy at a wavelength of 1072 nm has unexpectedly positive results when compared to 660 nm light. Moreover, an explanation of how an invention works is not a requirement of any criteria for patentability. See M.P.E.P. § 2138.05 (quoting Parker v. Fritolette, 462 F.2d 544, 547, 174 USPQ 321, 324 (CCPA 1972) ("[an] inventor need not understand precisely why his invention works in order to achieve an actual reduction to practice")).

Salansky proposes light treatment using a large range, *i.e.*, 400-2,000 nm. In contrast, the wavelengths recited in Claim 1 include a relatively small portion of Salansky's large range. Specifically, Applicant's Claim 1 recites "narrow band divergent electromagnetic radiation at a wavelength centered at, or about, 1072nm or at a wavelength centered at, or about, 1268nm..." Moreover, Salansky includes no specific examples falling within the claimed range. Furthermore, as set forth in the Dougal Declaration, Applicant has provided evidence of unexpected results. Therefore, Salansky does not teach or suggest the claimed invention with sufficient specificity and does not anticipate the claimed invention.

Moreover, the claimed invention is not rendered obvious by Salansky because Salansky does not teach or suggest the claimed range. However, even if Salansky presented a *prima facie* case of obviousness, Applicant notes that the M.P.E.P. § 2144.05 discusses that an applicant can rebut a *prima facie* case of obviousness by showing the criticality of the claimed range. “The law is replete with cases in which the difference between the claimed invention and the prior art is some range or other variable within the claims. . . . In such a situation, the applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range.” M.P.E.P. § 2144.05 (quoting *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990)). As discussed above, Applicant has demonstrated the criticality of the claimed range.

In view of the foregoing, Applicant respectfully submits that Claim 1 is clearly allowable over the cited art. Salansky does not disclose the claimed range with sufficient specificity. Salansky proposes a large range of wavelengths, and the claimed range is comparatively small. No examples of the range claimed by Applicant are discussed in Salansky. Additionally, Applicant has demonstrated unexpected results and the criticality of the claimed range.

Claims 5-26 depend from Claim 1 as amended and are therefore allowable for at least the reasons set forth above.

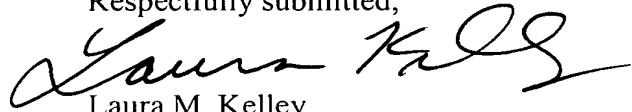
Moreover, regarding Claim 5, Salansky does not teach or suggest the limitations recited therein. Regarding the contention set forth in the Action at p. 6, fifth paragraph, the recited half angle divergence will ensure that “hot spots” are prevented, an aspect that may be critical or essential to the particular application.

Conclusion

In light of the above amendments and remarks, Applicant respectfully submits that the application is in condition for allowance and respectfully requests same. The Examiner is requested to contact the undersigned to resolve any remaining issues.

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Respectfully submitted,



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Carey Gregory

VERSION WITH MARKINGS TO SHOW CHANGES

In the Specification:

Please replace the paragraph at p. 4, lines 16-19 of the specification with the following paragraph:

-- Preferably, when the electromagnetic radiation is pulsed it is applied for pulse duration periods of at least 10-15 μ seconds and, more preferably, is applied at a frequency/repetition rate in the range 480-800 Hz. More preferably still, the frequency/repetition rate is at, or about, 600 Hz. --

In the Claims:

1. **(Three Times Amended)** An electromagnetic radiation therapy system comprising means for emitting **[narrow band]** divergent electromagnetic radiation at a wavelength centered at, or about, 1072nm **[and/or]** or at a wavelength centered at, or about, 1268nm so as to coincide with peak transmissions of a water molecule, the total bandwidth being restricted **[to simulate]** so as not to exceed the bandpass filter effect characterized by the transmission spectrum of the water molecule between 980nm and 1300nm, the system being capable of producing, at the site being treated, a radiation intensity of at least 50 μ Watts/cm² and up to 2 Watts/cm².

12. **(Three Times Amended)** An electromagnetic radiation therapy system according to Claim 1 wherein the electromagnetic radiation is pulsed, and the pulsed electromagnetic radiation is applied for pulse duration periods of at least 10-15 μ seconds.